



UNITED STATES PATENT AND TRADEMARK OFFICE

ck
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/772,164 | 02/03/2004 | Roger Y. Tsien | 02307E-152470US | 1874 |

20350 7590 01/06/2006

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

RUSSEL, JEFFREY E

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1654

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/772,164 | Applicant(s) TSIEN ET AL. | |
| | Examiner Jeffrey E. Russel | Art Unit 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1654

1. Claims 41-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 41-53 are dependent upon canceled claim 1. Assuming that these claims are amended to depend upon claim 40, claims 50-52 will be indefinite because it is not clear which N-terminal amino acid and/or which C-terminal amino acid is to be acetylated or amidated. Each of the polypeptide, the carrier polypeptide, and the target amino acid sequence will have N-terminal amino acids and C-terminal amino acids which will not necessarily be the same.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 40, 44, 45, and 48-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-24 of U.S. Patent No. 6,008,378.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The '378 patent claims a kit in which one of the components is a bonding partner which

Art Unit: 1654

preferably comprises a target sequence of SEQ ID NOS:1 or 4 and which also preferably comprises a heterologous carrier polypeptide. A kit comprising a compound suggests claims drawn to the compound per se.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 40-46, 48, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by the Berger et al article (J. Am. Chem. Soc., Vol. 78, pages 4483-4488). The Berger et al article teaches poly-L-cysteine comprising from 18 to 38 cysteine residues. See, e.g., page 4484, compound V and column 2, second full paragraph. Any six contiguous cysteine residues within the poly-L-cysteine of the Berger et al article correspond to Applicants' target amino acid sequence, with the remainder of the cysteine residues corresponding to Applicants' carrier polypeptide. Any single cysteine residue within the carrier polypeptide portion of the poly-L-cysteine of the Berger et al article corresponds to a fragment of a receptor, hormone, enzyme, or binding protein as is recited in instant claim 46. In view of the similarity in sequence between the poly-L-cysteine of the Berger et al article and Applicants' claimed polypeptide, the poly-L-cysteine will inherently specifically react with the biarsenical molecule recited in instant claim 40 to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the poly-L-cysteine of the Berger et al article and Applicants' claimed polypeptide to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than that of the Berger et al article.

Art Unit: 1654

6. Claims 40, 44-46, 48, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Dufлот et al (U.S. Patent No. 4,499,080). Dufлот et al teach peptides based upon E. coli enterotoxins. The peptides comprise the amino acid sequence Cys-Cys-Glu-Leu-Cys-Cys, and are conjugated to a carrier molecule which is either tetanus toxin or ovalbumin. See Examples I-VI. In view of the similarity in sequence between the peptides of Dufлот et al and Applicants' claimed polypeptide, the peptides will inherently specifically react with the biarsenical molecule recited in instant claim 40 to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides of Dufлот et al and Applicants' claimed polypeptide to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than that of Dufлот et al.

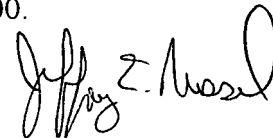
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel", with a stylized flourish at the end.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

January 3, 2006